DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
KN 543
Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
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December 15, 2000

VIA FEDERAL EXPRESS

William C. McMillan
President
Ultralite Enterprises, Inc.
390 Farmer Court
Lawrenceville, GA 30045

WARNING LETTER
(01-ATL-16)

Dear Mr. McMillan:

During an inspection of your establishment located in Lawrenceville, GA, on 8/21-28/00, Atlanta District investigator Fulton A. Varner determined that your establishment manufactures and distributes Phototherapy units. Phototherapy units are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure to promptly review, evaluate, and investigate by a designated individual (s) any complaint that represents an event which must be reported to FDA under part 803 of this chapter and to maintain those complaints in a separate portion of the complaints file or otherwise clearly identify them, as required by 21 CFR 820.198 (d). For example:

   a. No MDR procedures exist to define what is or not reportable, or how to report an MDR event.

   b. A review of product complaints from 1991 to 2000 revealed three instances of unreported MDR events involving patient burns. These complaints lacked any follow-up investigation or corrective action and are identified as UF Report #430014-1995-0001, Incoming Call Report Form dated 8/6/91, and Phone In Service Call Report dated 11/13/96.

2. Failure to automatically consider a service report a complaint when receiving a service report that represents an event which must be reported to FDA under part 803 of this chapter and process it in accordance with the requirements of Section 820.198, as required by 21 CFR 820.200 (c). For example: A review of the Phone In Service Reports for 1998-1999 revealed at least seven (7) instances in which these reports are actual customer complaints but not recorded and maintained as complaints. There was no investigation or follow-up of the complaints identified as Service Call Reports dated 2/24/00, 8/28/00, 9/21/99, 9/10/99, 8/30/99, 8/25/99, 8/23/99, 7/20/99, 2/18/99, and 5/26/98.

3. Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality, ensuring that the quality policy is understood, implemented, and maintained at all levels of the organization, as required by 21 CFR 820.20 (a). For example, no quality policy currently exists that defines the intentions or directions with respect to quality.

4. Failure to appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for, ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part, and reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20 (3) (i) and (ii). For example:

    a. No management representative has been appointed to assure that the quality system is effectively established and maintained.

    b. Management with executive responsibility has failed to ensure the establishment and maintenance of an adequate quality system as determined by the failure to take any corrective actions following significant deficiencies found during previous inspections by the Food and Drug Administration (FDA).

5. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20 (c). For example, no management reviews are currently conducted, nor are any procedures in place to assure that your quality system is adhering to the Quality System regulation.

6. Failure to conduct quality audits in accordance with established procedures and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, current internal audits are not conducted at the specified periodic interval required by current procedures, DMR 5.8. The procedures require yearly audits, and a listing of the audits performed are dated 1991 and 1997.

7. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30 (i). For example, no design change control procedures are currently in place to evaluate any changes to the original design of the devices being produced.

8. Failure to maintain device master records (DMR's) for each type of device including or referring to the location of device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications, as required by 21 CFR 820.181 (a). For example, there are no defined raw material specifications for the UVA and UVB bulbs received which define the acceptance parameters of the irradiation transmittance and wavelength profiles for each lot of bulbs received.

9. Failure to, validate computer software for its intended use according to an established protocol when computers or automated data processing systems used as part of production or the quality system, as required by 21 CFR 820.70 (i). For example, the software utilized in th[redacted]

[redacted] which controls and monitors UVA and UVB irradiation exposure a patient receives, has not been validated.

10. Failure to establish and maintain procedures for implementing corrective and preventive action including requirements for analyzing processes, quality audit reports, quality records, returned product, sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100 (1). For example:

    a. No corrective and preventive action procedures exist which define the requirements of the Quality System regulation.

    b. Sources of product quality problems have not been identified and corrective action initiated.

11. Failure to ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use, as required by 21 CFR 820.70 (g). For example, there are no quality control checks being conducted to assure that electronic grounding devices (i.e., hand straps, work mat, and electronic component storage shelves) are properly grounded to prevent ESD damage to sensitive components.

12. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, including provisions for handling, preservation, and storage of equipment so that its accuracy and fitness for use are maintained, as required by 21 CFR 820.72 (a). For example, no inspectional, testing, or calibration has been established for the [redacted] and calipers currently utilized.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of Section 502 (t)(2) of the Act, in that you failed or refused to furnish any material or information required by or under section 519 respecting the device. Specifically, you failed to submit MDR reports to FDA after receiving an incoming call dated 8/6/91 in which two patients received second degree burns on all parts of their bodies. Another incident dated 11/13/96 involved two patients receiving second degree burns (severe blistering). You failed to investigate and evaluate the cause of these incidents as required by 21 CFR, Part 803.50(b)(2). You also failed to document both the deliberations and decision-making processes used to determine if the device related event was or was not reportable, as required by 21CFR 803.18(b)(1)(i).

On 12/11/00, members of my staff met with you at the Atlanta District Office. During this meeting, we advised you to hire a consultant to help bring your firm into compliance with FDA's regulations, since by your own admission, you indicated that you are not knowledgeable about the QS/GMP regulation. Enclosed you will find a copy of the device Quality System regulation, 21 CFR, Part 820. You indicated that you understood the need to hire a consultant. We provided you with a document entitled "Selecting a Consultant?" You indicated that your firm has just started to address the software validation and that it will take three to six months to complete. We reviewed the previous FDA-483's with you and asked if there were any issues that you did not understand. You indicated that you understood all of the observations. We informed you that we were troubled by your firm's lack of a response to our 10/99 Warning Letter as well as your firm's lack of any corrective actions following the 9/99 inspection. We explained the regulatory actions available to FDA, should our follow-up inspection reveal continued violations of the QS/GMP and MDR regulations.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance for Class III devices for which a 510(k) premarket notification or Premarket Approval application (PMA) has been submitted, and Certificates to Foreign Governments for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device QS/GMP regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by you that you have reviewed the consultant's report and that your establishment has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant. A copy of this guidance was also provided to you during our meeting on 12/11/00.

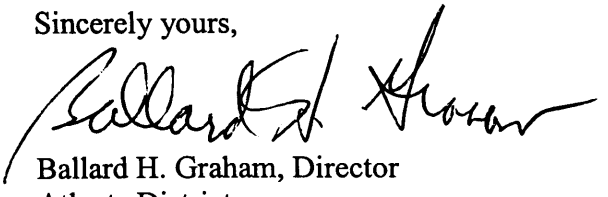
The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections should be submitted to this office by the following dates:

- Initial certifications by consultant and establishment- 5/1/01
- Subsequent certifications- 6/1/02 and 6/1/03.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you will be taking to comply with our request. Your response should be sent to Serene A. Kimel, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Enclosures